UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,126	07/23/2001	Padma S. Bagaria		2532

7590 11/17/2004

TED MASTERS
23344 8TH STREET
NEWHALL, CA 91321

EXAMINER	
NGUYEN, BAO THUY L	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/910,126	BAGARIA, PADMA S.	
	Examiner	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendment filed on 12 October 2004 and Request for Examiner Affidavit filed on 23 August 2004 have been received. Claims 10-16 are pending.

2. All rejections not reiterated herein below are withdrawn in view of the amendment to the claims.

Request for Examiner Affidavit

3. The request for an Examiner Affidavit under 37 CFR 1.104 (d) (2) is denied. Applicant traverses the 35 USC 112 rejections made in the previous office action, specifically, all of item 3 and the second and fourth paragraphs of item 4 and request an affidavit in accordance with 37 CFR 104 (d) (2). This rules calls for an affidavit "[w]hen a rejection in an application is based on facts within the personal knowledge of an employee of the Office"; however, this is not the case in the instant application. The rejection and office action clearly states that the broad scope of the claims are not fully enabled by the specification, and specific explanation was given as to what is enabled by the specification. This statement is not based on *facts within the personal knowledge* of the office, rather, it is based on the lack of teachings in the specification so that *one skilled in the art and make and use the invention commensurate in scope with the claims.*

Claim Rejections - 35 USC § 112, first paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 10-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for detecting human blood using labeled anti-Hb antibodies which are captured and detected, does not reasonably provide enablement for a labeled anti-Hb antibody in which the label is released from the antibody thereby providing a visual indication. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification teaches conventional labels such as enzymes and particulate labels conjugated to antibodies to hemoglobin. The specification does not teach *how these labels are conjugated* to the antibodies such that *binding* of a complex comprising hemoglobin and labeled antibody to an immobilized capture reagent *allows the labels*, i.e. enzymes, *to be released from the antibodies* thereby providing a visual indication. No example is given nor any other discussion of releasable labels is found. In conventional assays, binding of a labeled complex to the capture reagents localized the label in a detection area, and the addition of substrate for the enzyme label allows color to develop, thus detection is made. Or in the case of particulate direct labels, binding of the labeled complex localized the visual direct labels in the detection area enabling detection. Generally, neither labels such as enzymes nor particulate labels is released from the antibody, as clearly demonstrated by the prior art of record cited in the "Background Art" of the specification. In instances where labels are released, a set of specific condition must be met before such labels are operable. Roberts, for examples, teaches the use of liposome-encapsulated labels in test strips. Roberts teaches that in order for the signal from the

labels to be read, liposome lysing reagents must be employed. Without such lysing reagent, the label is not released from the liposome. See entire document.

Because the specification does not teach how skilled in the art may make and use releasable labels it would require undue experimentation to make and use the invention as claimed.

Response to Arguments

6. Applicant's arguments filed in the Request for Examiner Affidavit dated 23 August 2004 and in the Amendment dated 12 October 2004 have been fully considered but they are not persuasive.

Applicant argues that the conjugation of labels to antibodies is well known in the art and gives examples of how conventional conjugation is performed. It is Applicant's position that the claims are fully enabled because the release of the labels from the antibody to which they have been conjugated is described in the specification.

As stated in the previous office action and reiterated herein above, the specification does not enable the broad scope of the claims. It is not the conjugation of the labels per se, that is the questions. It is the question of *how* has the labels been conjugated, or what techniques are used by applicant *that allows the label to be released* from the antibody when the binding occurs. Because applicant states that the labels are those well known and conventional in the art such as enzymes and colloidal labels, and the method of conjugating these labels to the antibodies are well known and conventional in the art, the prior art of record, specifically those teachings the same conventional conjugation techniques, *does not teach the release of the labels* from the antibody *when binding between the labeled-antibody and the immobilized antibody occurs.* In addition,

applicant also fails to teach a method where these labels are *released* from the anti Hb antibodies after binding occurs between a complex comprising the labeled-anti-Hb-antibodies, the analyte hemoglobin and the immobilized anti Hb antibody, or between the labeled-antibodies and the immobilized control antibodies. Even though applicant asserts that the specification teaches such a release, this is not persuasive. The specification does not teach how such release occurs. The specification does not teach how the conjugation has been done so that release, as claimed, can occur. If the same labels and the same conjugation technique as those in the prior art is used, as argued, and those of the prior art does not get released from the antibody, how is it that Applicant's method allows this release to occur?.

Because these are well known labels that have been conjugated to the antibodies using conventional techniques, and because both the specification and the prior art of record fails to teach a mechanism by which the labels are *released* from the antibodies after binding occurs so that detection of the *released* labels can be detected without some sort of bond-breaking reagent, the claims are not enabled by the specification. As stated previously and reiterated above, in instances where labels are *released,* a set of specific condition must be met before such labels are operable. Roberts, for examples, teaches the use of liposome-encapsulated labels in test strips. Roberts teaches that in order for the signal from the labels to be read, liposome lysing reagents must be employed. Without such lysing reagent, the label is not released from the liposome.

Furthermore, Applicant argues that prior art documents cited in the specification teaches techniques of labeling and the release of labels is described in the specification.

This argument has been fully considered but is not persuasive. It is not the office's position that the labels cannot be conjugated to the antibodies, rather the rejection is that once the labels is conjugated to the antibodies using these conventional techniques, neither Applicant

nor the prior art of record teaches how it can be *released by virtue of binding between the labeled-antibodies and the immobilized control antibodies.* None of the cited prior art teaches this *release,* and Roberts teaches that in order for labels to be release, a lysing reagent must be employed. Therefore, it is unclear how Applicant's method allows this *release* to occur.

Claim Rejections - 35 USC § 112

7. Claims 10-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 and 14 are vague and indefinite because it is unclear how releasing the labels from the antibodies provides a visual indication. It would appear that once the labels are released from the antibodies, they are no longer localized in the detection zone and would therefore, migrate away from such zone, thus any color that developed would be lost.

Response to Arguments

8. Applicant argues that as soon as the color is released, it is likely absorbed/adsorbed on the membrane. Some (but not all) of the labels may get washed away if there is an excess of it causing the entire window to have a pinkish background color but the concentrated pinkish color in the specific test region location would still clearly give a positive indication.

This argument is not persuasive. First, it is noted that no indication of a specific color is recited in the claim, therefore, it is assumed that the pinkish color argued by applicant refers to the label itself. Second, assuming, arguendo, that the labels get released from the antibody, common sense dictates that since the membrane is such that it allows the migration of various

reagents, including the labels, from the sample introduction station to the test station and the control station, arranged in series such as illustrated in the drawings, such a membrane will also allows the migration of any color that is not specifically captured by an immobilized reagent. Therefore, it appears that once the labels are released from the capture antibodies, they continues to migrate with the sample liquid front away from the test zone or control zone, thus any color that developed would be lost.

As demonstrated by prior art cited by Applicant in the Background, specification, page 4, May (GB 2,204,398) teaches that absorption or adsorption and retention of a reagent in a localized location on a test membrane requires the additional step of drying. When not covalently bonded to the membrane, labeled reagent is only retained in the zone when the material (i.e. membrane) is in the dry state but will migrate through the membrane in the wet state. See specifically page 35. Therefore, labels that are released from the capture reagent will migrate, at the same rate, out of the test zone or control zone and no concentration of color can occur as argued.

Applicant also argues that US Patent 6,686,167 contains a specification and claims which are almost identical to those of the instant invention and that it is inconsistent for the Office to deem the disclosure of one application to be sufficient and then take the position that an almost identical application does not provide a sufficient disclosure.

9. This argument has been fully considered. It is noted that although the specifications are similar, the claims are not. US 6,686,167 *does NOT claim* a method in which the *label is released* from the antibody to which it has been conjugated. In contrast, the *instant specification*, while being enabling for a method for detecting human blood using labeled anti-Hb antibodies which

are captured and detected, *does not reasonably provide enablement* for a labeled anti-Hb antibody in which *the label is released* from the antibody thereby providing a visual indication.

10. The drawings are acceptable for examination purposes.

Conclusion

11. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 8:00 a.m. -3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641
11/4/04